UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,708	10/09/2001	Youmin Shu	16U 102 R1	4218

23599 7590 06/14/2004

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
ANDRES, JANET L	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/971,708	SHU ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,9-20 and 22-24* is/are pending in the application.

4a) Of the above claim(s) *1,3-7 and 9-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 March 2004 has been entered.

Claims 1, 3-7, 9-20, and 22-24 are pending in this application. Claims 1, 3-7, and 9-20 are withdrawn from consideration as being drawn to a non-elected invention. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink on p. 4, lines 24-25. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 101

3. Claims 22-24 are rejected under 35 U.S.C. 101 as lacking either a specific and substantial asserted utility or a well-established utility for reasons of record in the office action of 25 July 2003 and 5 January 2004.

Applicant states that ephrins are members of a recognized family of tyrosine kinases. Applicant further states that EphA6 is a tyrosine kinase and reiterates that ephrins play functional roles in pattern formation and development. Applicant argues that ephrin receptors have a characterized tyrosine kinase activity and that ligand binding results in dimerization and

transphosphorylation. Applicant further argues that the EphA6 is highly restricted to the brain, pancreas, and testis and that the fact that it is found in other cell types does not detract from its utility as a tissue marker. Applicant additionally argues that it can be used to detect metastatic pancreatic cells. Applicant further argues that it can be used as a marker in stem cell engineering. Applicant argues that tissue specificity has been published as adequate for a utility, citing example 12 of the utility guidelines. Applicant argues that there is no reason why specificity of normal tissue would not also satisfy the requirement. Applicant further cites the written description guidelines as providing an example of a receptor whose function is associated with glial cell differentiation.

Applicant's arguments have been fully considered but have not been found to be persuasive.

The claims are drawn to a method of detection of KSE132, which is known in the art as EphA6, in pancreatic cells. As stated in the previous office actions, both the polypeptide and the method of use lack utility. That the polypeptide is an ephrin does not endow it with a utility. That ephrins share properties common to tyrosine kinases such as dimerization and phosphorylation provides no guidance as to their function; this process is merely the method by which intracellular signals are initiated and provides no information as to what those signals are or what their ultimate effect on the cell might be. That ephrins, generally, are somehow associated in various processes of differentiation does not teach the artisan how to use this particular ephrin or a method of identifying it. Applicant has disclosed no association of this protein with any developmental change or with any other process. Thus, there is no specific and substantial utility associated with the protein or with its detection in a particular cell type. The

function of the protein is not known, it is not known to be associated with any disease, and thus there is no benefit to be gained from detecting its presence. Use of the protein as a marker for pancreatic cells is not a specific utility; it could apply to any protein and does not depend on the particular properties of KSE132/EphA6. Neither the specification nor the prior art identifies any association with any disease; it is not, for example, known to be differentially expressed in metastatic pancreatic cells. Thus its use in identifying such cells would simply be to identify cells of pancreatic origin and, as stated above, is not a specific utility, because it does not depend on any properties of the protein itself. For the same reason, its potential use as a marker for stem cell differentiation is not specific to the protein. Neither example 12 of the utility guidelines nor example 6 of the written description guidelines are analogous circumstances. Example 12 of the utility training materials is of a receptor found to be differentially expressed on melanoma cells as opposed to normal skin cells. This differential expression is a specific property of that protein; its expression is altered in a particular cell type in response to cancerous changes. However, as stated previously, Applicant has disclosed no properties that are particular to the instant protein that would impart its detection with a specific utility. It is merely expressed in some tissues and not in others. Example 6 of the written description guidelines does not directly address utility. However, the protein is glial specific and associated with glial cell differentiation, unlike the instant protein, which is not specific to pancreas or any other tissue and is not known to function in pancreatic differentiation. In addition, the exemplified protein was found to be useful to identify agents that regulated differentiation and that thus would be of interest as therapy for gliomas; no such specific utility could be inferred from the general statement that ephrins are involved in development.

Further, the specification merely states that the protein is expressed in pancreas and thus could be used, generally, in diseases of the pancreas as well as other tissues. There is no guidance to indicate that the protein itself is detectably expressed in pancreatic cells, in metastatic pancreatic cells, and not in stem cells. No results for stem cells are shown. In addition, all that is provided are PCR results showing message regulation. This is not sufficient guidance to allow the skilled artisan to predict that sufficient protein would be expressed and could be identified in pancreatic cells, including metastatic pancreatic cells, and not in stem cells. Thus, its utility as a marker is also not a substantial utility; clearly, further research would be required before it could be used in any diagnostic fashion, or to differentiate pancreatic cells from stem cells.

4. The rejection of claims 22-24 under 35 U.S.C. 112, first paragraph, as lacking enablement because the invention lacks utility, is maintained for reasons of record in the office action of 5 January 2004.

Applicant argues as set forth above. Since, for the reasons stated above, Applicant's arguments with respect to utility are not found to be persuasive, the invention lacks utility and one skilled in the art would not know how to use it.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.
Primary Examiner

10 June 2004